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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,644	09/18/2001	Eric Silverberg	1893	1184

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
10/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/955,644	SILVERBERG ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,9-19 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7 and 9-19, 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE filed 07/27/2010.

Claims 1, 3-7, 9-19, 21-23 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/27/2010 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4,-7, 9-14, 18, 19, 21, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. (JP 61-126020, IDS filed 03/27/2009).

Currently amended claim 1 is directed to a non-reactive pressure sensitive adhesive composition comprising an acrylic polymer and a therapeutic agent, wherein the acrylic polymer

(i) is prepared from monomers selected from the group consisting of alkyl acrylate monomers, alkyl methacrylate monomers, polymerizable non-cyclic nitrogen-containing monomers and mixtures thereof,

wherein said alkyl acrylate monomers and alkyl methacrylate monomers have up to about 18 carbon atoms in the alkyl group,

and wherein said polymerizable non-cyclic nitrogen-containing monomers are selected from the group consisting of t-octyl acrylamide, dimethyl acrylamide, diacetone acrylamide, t-butyl acrylamide, i-propyl acrylamide, N-phenyl acrylamide, vinylacetamides, nitriles, and mixtures thereof,

and wherein said alkyl acrylate monomers and/or alkyl methacrylate monomers are present in the acrylic polymer in amounts of from about 50 to about 98%, based on a dry weight basis of the total monomer weight of the acrylic polymer, and said polymerizable non- cyclic nitrogen-containing monomers are present in the acrylic polymer in amounts of from about 2 to about 50%, based on a dry weight basis of the total monomer weight of the acrylic polymer,

(ii) lacks functional groups containing reactive hydrogen moieties and

(iii) contains no post-polymerization chemical crosslinking.

Currently amended claim 12 recites a transdermal drug delivery device comprising a layer of the non-reactive pressure sensitive adhesive as set forth and backing layer.

Currently amended claim 22 recites a transdermal drug delivery device comprising the non-reactive pressure sensitive adhesive as set forth.

Nakagawa discloses patch for external use comprising active agent in an acrylic adhesive layer. The acrylic adhesive is a copolymer of (meth)acrylic acid alkyl ester and a monomer having an amide bond which is preferably diacetone acrylamide (claims 1-3). Example 1, page 120 of the reference, discloses copolymer composition composed of 30% 2-ethylhexyl methacrylate, 61% butyl acrylate which form 91% of alkyl acrylate monomer, and 9% diacetone acrylamide. The amounts of the monomers as disclosed by the reference falls within the claimed ranges, therefore the reference anticipates the claims. The reference disclosed (meth)acrylic acid alkyl ester having 1-8 carbon atoms. Monomers having an amide bond further include octyl-acrylamide, dimethyl acrylamide, and butyl acrylamide. See page 118, right column. The acrylic polymer disclosed by the reference used the same monomers in the same amounts, therefore, inherently the polymer is lacking functional groups containing reactive hydrogen moieties and the adhesive is inherently non-reactive containing no post-polymerization chemical crosslinking as required by the present claims 1, 12 and 22. The Tg as claimed by claim 4 is inherent by the disclosure of the reference because the reference discloses polymer comprising the same monomers in amounts falling within the claimed ranges. The

adhesive composition forms an adhesive layer on film, which is a backing layer, and further having a support, which reads on release liner (page 120, left column and example 1). The reference disclosed non-steroidal anti-inflammatory agents.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagawa in view of Akemi (EP 0531938, of record).

Applicant Claims

Applicant's claim 3 is directed to a nitrile, which nitrile is methacrylonitrile or 2-cyanoethylacrylate.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The teachings of Nakagawa are previously discussed in this office action.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Nakagawa teaches monomer having an amide bond, and teaches acrylonitrile in page 119, left column, first paragraph, as suitable for inclusion in the polymer of the reference, however, the reference does not explicitly methacrylonitrile or 2-cyanoethylacrylate as instantly claimed by claim 3.

Akemi teaches medical preparation for percutaneous absorption of drugs (abstract). The preparation comprises pressure sensitive acrylic based layer obtained

by polymerizing 60-98% by weight of alkyl(meth)acrylate monomer having 4 to 15 carbon atoms in the alkyl moiety and from 2-40% by weight of monomer copolymerizable with the alkyl (meth)acrylate (page 4, lines 13-19; page 26, claim 5). The monomer copolymerizable with the alkyl (meth)acrylate includes butyl acrylamide, dimethyl (meth)acrylamide, and (meth)acrylonitrile (page 4, lines 29, 36).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, the prior art recognized the equivalency between butyl acrylamide and dimethyl (meth)acrylamide taught by Nakagawa and (meth)acrylonitrile to polymerize with alkyl(meth)acrylate monomer.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an acrylic adhesive polymer of (meth)acrylic acid alkyl ester and a monomer having an amide bond as taught by Nakagawa, and use (meth)acrylonitrile taught by Akemi. One would have been motivated to do so because Akemi recognized the equivalency between monomer having an amide bond taught by Nakagawa and (meth)acrylonitrile as suitable polymer to polymerize with alkyl(meth)acrylate monomer in percutaneously absorbed preparation. One would reasonably expect formulating an acrylic adhesive polymer of (meth)acrylic acid alkyl ester and (meth)acrylonitrile to deliver active agents effectively to the skin.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

8. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagawa in view of Miranda et al. (US 5,474,783, currently listed on PTO 892).

Applicant Claims

Applicant's claims 15-17 are directed to the active agent is being fentanyl.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The teachings of Nakagawa are previously discussed in this office action.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Nakagawa teaches non-steroidal anti-inflammatory analgesic, however, does not explicitly teach fentanyl as an active agent delivered by the claimed patch to the skin.

Miranda teaches transdermal drug delivery device that permits selectable loading of drug into dermal formulation and adjustment of delivery rate the drug from the composition through the dermis, while maintaining acceptable shear, tack, and peel adhesive properties (abstract). The dermal formulation comprises up to 96% polyacrylate copolymer comprises alkyl acrylate monomer copolymerized with monomer

having functional groups including methacylamide (col.9, lines 21-59). Preferred drugs to be delivered by this transdermal device include fentanyl and non-steroidal anti-inflammatory drugs as evident by claim 1 of the reference.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, the prior art recognized the equivalency between fentanyl and non-steroidal anti-inflammatory active agents in terms of transdermal delivery from adhesive comprising acrylate polymers comprises alkyl acrylate monomer copolymerized with monomer having functional groups including methacylamide.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an acrylic adhesive polymer of (meth)acrylic acid alkyl ester and a monomer having an amide bond as taught by Nakagawa, and use adhesive to deliver fentanyl taught by Miranda. One would have been motivated to do so because Miranda recognized the equivalency between non-steroidal anti-inflammatory drugs taught by Nakagawa and fentanyl as suitable for transdermal delivery from adhesive preparation comprising alkyl(meth)acrylate monomer and functional containing monomer. One would reasonably expect formulating an acrylic adhesive polymer of (meth)acrylic acid alkyl ester and monomer having an amide bond that delivers fentanyl effectively to the skin of a patient in need of such treatment.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

9. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakagawa.

Applicant Claims

Applicant's claim 23 is directed to monomer composition of the acrylic polymer is 45 % by weight 2-ethylhexyl acrylate, 35 % by weight methyl acrylate and 20 % by weight of an N-substituted acrylamide monomer.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The teachings of Nakagawa are previously discussed in this office action.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Nakagawa teaches 2-ethylhexyl acrylate, and methyl acrylate, and teaches the combination of two (meth)acrylic acid alkyl ester monomer in the polymer composition, and further teaches the same amount of the monomers in the polymer from 1-50%, however, the reference does not explicitly teach the specific combination and amounts as instantly claimed by claim 23.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233. This is the case here because all the claimed monomers are taught by the prior art and the claimed amounts overlaps with those taught by the prior art. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. **See MPEP 2144.05 [R-5].**

Applicants failed to show unexpected results obtained from using the specific monomers combination in the specific amounts.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

10. Applicant's arguments with respect to claims 1, 3-7, 9-19, and 21-23 have been considered but are moot in view of the new ground(s) of rejection.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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